K060052

APR 19 2006

GE Healthcare
Technologies

510(k) Summary of Safety and Effectiveness

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

Submitter:

Name:	GE Medical Systems, LLC (GE Healthcare)
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Date Prepared:	11 November 2005

Product Identification:

Proprietary Device Names:	GE LightSpeed Xtra CT Scanner System *Available also as* GE LightSpeed RT Pro[16]
Common Name:	CT Scanner
Classification Name:	Computed Tomography X-ray System (21 CFR 892.1750, Product Code JAK)

Predicate Device(s):

GE LightSpeed 5.0 CT Scanner System	K030420

Device Description:

The LightSpeed Xtra CT Scanner System is composed of a gantry, patient table, operator console, power distribution unit (PDU), and interconnecting cables. The system includes image acquisition hardware, image acquisition and reconstruction software, and associated accessories.

The system generates images through the computer reconstruction of data acquired at different angles of the same axial plane. The gantry can rotate at up to 0.5 seconds per rotation, and can acquire up to 16 slices of data with a maximum total coverage of 20mm in the axial direction. The system may be operated in both axial and helical scan modes.

The system features an 80cm diameter wide bore to accommodate large patients and radiation therapy planning immobilization devices, to allow easy access during interventional procedures, and for ease of patient positioning.

The LightSpeed Xtra system is also available as the LightSpeed RT Pro[16], which features a unique accessory package designed to assist planning of radiation therapy procedures.

Intended Use:

The GE LightSpeed Xtra CT Scanner System is indicated for head and whole body X-ray Computed Tomography applications.

The system is capable of generating images for the guidance of minimally invasive procedures such as biopsy and ablation of tumors and pathology.

The system allows imaging of obese patients, up to and including the morbidly obese population (BMI > 40).

When used in the LightSpeed RT Pro[16] configuration:

The system acquires CT anatomical images that are clinically useful in the simulation and planning of radiation therapy for the treatment of cancer.

Comparison with Predicate:

The LightSpeed Xtra CT Scanner System represents a modification to the legally marketed LightSpeed 5.0 scanner (510(k) number K030420). The LightSpeed Xtra is an evolutionary change to the LightSpeed product line, and includes many features, functions, software, and hardware that are common to previous generations, including the LightSpeed 4.0 (K013561) 16 slice system, the LightSpeed 3.0 (K002978) 8 slice system, and LightSpeed 2.0 (K000300) 4 slice system. It has the same technological characteristics and operating principles, is comparable in key safety and effectiveness features, and uses the same basic design, construction, and materials.

In the opinion of GE Healthcare, the LightSpeed Xtra CT Scanner System is of comparable type and is substantially equivalent to currently marketed head and whole body X-ray computed tomography systems that comply with the same or equivalent standards and have similar intended uses.

Conclusion:

LightSpeed Xtra is an evolutionary modification to the LightSpeed 5.0 scanner (K030420), does not result in any new potential safety risks, and performs as well as or better than devices currently on the market. LightSpeed Xtra will be certified to comply with the X-ray requirements of 21CFR1020.30 and 1020.33, as well as the safety requirements of UL 60601-1, and IEC 60601-1 and associated collateral and particular standards. GE considers the LightSpeed Xtra CT Scanner System to be equivalent to other marketed devices with similar indications for use and meeting similar standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 19 2006

GE Medical Systems, LLC (GE Healthcare)
% Mr. Tamas Borsai
Program Manager, Third Party Review Program
TÜV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K060052
Trade/Device Name: GE LightSpeed Xtra CT Scanner System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulation Number: 21 CFR 892.5840
Regulation Name: Radiation therapy simulation system
Regulatory Class: II
Product Code: JAK and KPQ
Dated: April 3, 2006
Received: April 4, 2006

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060052

Device Name: GE LightSpeed Xtra CT Scanner System

Indications for Use:

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When used in the LightSpeed RT Pro^{16} configuration:

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Prescription Use X **AND/OR** **Over-the-Counter Use** _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060052